REMARKS

Applicants understand that the amendment in response to the December 23, 2008 Final Office Action has not been entered. By this Amendment, applicants have canceled claims 15, 23 and 24 and amended claim 16. No issue of new matter is raised by these amendments. Accordingly, applicants respectfully request that the Examiner enter and consider these amendments.

Priority

In the Final Office Action, the Examiner indicated that the claimed priority of PCT International Application PCT/IB03/05673, filed December 1, 2003 must be perfected in order for the subject application to have an effective filing date of the December 1, 2003. In response, applicants previously submitted an Application Data Sheet wherein such priority is claimed.

Rejection Under 35 USC § 112, Second Paragraph

The Examiner rejected claims 23 and 24 under 35 U.S.C. 112, second paragraph, as indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. In response, but without conceding the correctness of the Examiner's ground of rejection, applicants have canceled claims 23 and 24 thereby rendering moot the Examiner's ground of rejection.

Rejections in view of Pacioretty and Babish

The Examiner rejected claims 15-22 and 25-28 under 35 U.S.C. 102(e) as anticipated by Pacioretty and Babish, and claims 15, 23 and 24 under 35 U.S.C. 103(a) as obvious over Pacioretty and Babish.

In response, applicants first note that claims 15, 23, and 24 have been canceled thereby rendering moot the Examiner's ground of rejection as to these claims. Applicants respectfully traverse the Examiner's rejection as to claims 16-22 and 25-28.

Pacioretty and Babish disclose a method of treating fat maldistribution resulting from anti-retroviral treatment of HIV-1 infection in a subject comprising administering a pharmaceutically effective dose of a docosahexaenoic acid in combination with a pharmacologically effective dose of a thiol-containing compound or a bioavailable form of trivalent chromium. Pacioretty and

Babish further disclose at paragraph 62 that preferably a daily dose of the present composition would be formulated to deliver about 0.05 to 20 g of conjugated fatty acid per day.

Applicants maintain that the cited prior art does not disclose the claimed invention wherein DHA alone is administered at an amount higher than or equal than to 100 mg/day to a patient concomitantly receiving anti-retroviral therapy is effective in the treatment of lipodistrophy.

In addition, Pacioretty and Babish disclose that the combination of at least 2 ingredients: DHA and a thiol-containing compound or a bioavailable form of trivalent chromium, is the *one effective against fat maldistribution.* Pacioretty and Babish do not disclose, and nowhere can it be derived either explicitly nor implicitly, that *DHA alone* demonstrates this pharmacological and beneficial effect.

In contrast, applicants' invention as recited in amended claim 16 is directed to a method of treatment of lipodistrophy *consisting of* administering an amount higher than or equal to 100 mg/day of DHA alone in a patient simultaneously submitted to antiretroviral therapy.

In view if the remarks above, applicants maintain that Pacioretty and Babish do not anticipate claim 16 as now amended or claims dependent therefrom, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Rejection over Holstein et al. in view of Connor et al.

The Examiner rejected claims 15-28 under 35 U.S.C. 103 as obvious over Holstein et al. in view of Connor et al.

In response, applicants again note that claims 15, 23 and 24 have been canceled thereby rendering moot the Examiner's ground of rejection as to these claims. Applicants respectfully traverse the Examiner's ground of rejection as to claims 16-22 and 25-28.

Applicants again respectfully disagree with the Examiner's interpretation that hyperlipidemia is a form of lipodystrophy.

Applicants submit herewith a print-out of MeSH from the U.S. National Library of Medicine's official vocabulary used for indexing articles for MEDLINE/PubMed. According to MeSH, lipodystrophy is defined by:

A collection of heterogenous conditions resulting from defective LIPID METABOLISM and characterized by ADIPOSE TISSUE atrophy. Often there is redistribution of body fat resulting in peripheral fat wasting and central adiposity. They include generalized, localized, congenital, and acquired lipodystrophy.

According to MeSH, hyperlipidemia is defined as: *Conditions with excess LIPIDS in the blood*

In the categories scheme provided by MeSH for "Lipid Metabolism Disorders", lipodystrophy and hyperlipidemia are presented as different species. The group of hyperlipidemias is categorized by MeSH as a species of dyslipidemias. Dyslipidemias and lipodistrophy are different groups within the genus "Lipid Metabolism Disorder".

Applicants point out that consistent with the Examiner's interpretation, lipodistrophy results from defective metabolism of fat, but it is additionally characterized by atrophy or redistribution of body fat. In contrast, hyperlipidemia is characterized by excess lipids in the blood. Applicants maintain that therefore these two terms deal with different physiological matters, i.e. blood versus adipose tissue, and different concepts, i.e. lipids excess versus redistribution of fat. Applicants agree that hyperlipidemia may be associated with lipodistrophy, but that this association in no way implies that hyperlipidemia and lipodistrophy are similar or subsets of each other and that an effective treatment for one would be an effective treatment for the other.

In view if the remarks above, applicants maintain that Holstein et al. in view of Connor et al. do not render obvious claim 16 as now amended or claims dependent therefrom, and respectfully request that the Examiner reconsider and withdraw this ground of rejection.

Reconsideration and allowance of all the claims herein are respectfully requested.

Respectfully submitted,

May 26, 2009

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1: **Lipid Metabolism Disorders** Links

Pathological conditions resulting from abnormal anabolism or catabolism of lipids in the body.
Year introduced: 2007

Subheadings. This list includes those paired at least once with this heading in MEDLINE and may not reflect current rules for allowable combinations.

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- **Lipid Metabolism Disorder**
- **Metabolism Disorder, Lipid**
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Diseases Category
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Dyslipidemias
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Lipid Metabolism, Inborn Errors
Lipidoses
Cholesterol Ester Storage Disease +
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